Supreme Court, U.S.
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No. 01-344

In The

Supreme Court of the United States

TOMMY G. THOMPSON,
SECRETARY OF HEALTH AND HUMAN
SERVICES, ET AL.,

Petitioners,

v.

WESTERN STATES MEDICAL CENTER, ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED FOR REVIEW

Do provisions of the Food and Drug Administration Modernization Act of 1997 that permit compounding only if "the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug" violate the First Amendment?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT PURSUANT TO RULE 29.6

The Respondents are: Western States Medical Center Pharmacy, a Nevada corporation; Women's International Pharmacy, a Wisconsin corporation; Health Pharmacy, a Wisconsin corporation; College Pharmacy, a Colorado corporation; and Wedgewood Village Pharmacy, a New Jersey corporation.*

None of the Respondents has a parent corporation. None of the Respondents has stockholders that are publicly held companies owning 10% or more of the stock in the corporation.

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*Counsel for the corporations listed above no longer represent Lakeside Pharmacy and ApotheCure.

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STATEMENT OF THE CASE

Because Petitioners' Statement of the Case is neither accurate nor complete, Respondents, pursuant to Supreme Court Rule 15.2, correct the inaccuracies in Petitioners' Petition and refer the Court to the facts as set forth in (1) Judge Ezra's order granting Respondents' summary judgment motion (App., 18(a));[1] (2) the Ninth Circuit's opinion (App., 2a-3a); and (3) Respondents' verified complaint.

INACCURACIES IN THE PETITION

1. Contrary to Petitioners' suggestion (Petition, 2, 17-18), this case has *nothing* to do with the distribution of drugs that are not generally recognized as safe and effective. Rather, this case deals *solely* with whether the absolute restrictions on truthful advertising and solicitation contained in the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), 21 U.S.C. §§ 353a(a) and (c), violate the First Amendment.

2.a. Although irrelevant for First Amendment purposes, it is not true, as Petitioners claim, that "[w]hen a pharmacy compounds a drug, the pharmacy creates a 'new drug' because the compounded product is not generally recognized as safe and effective." (Petition, 4.) Nor is it true, as Petitioners suggest (Petition, 4-6), that prior to the enactment of FDAMA, compounding was illegal.

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[1] Cites to the appendix attached to Petitioners' Petition are designated "App. ___."

b. Compounding was not illegal before FDAMA, even though according to the FDA's Compliance Policy Guide ("CPG") the FDA conferred upon itself discretion to "initiate federal enforcement action against entities and responsible persons when the scope and nature of a pharmacy's activity raise[s] the kinds of concerns normally associated with a manufacturer and that results in significant violation of the new drug adulteration or misbranding provisions of the Act." (App., 76a; FDA Compliance Policy Guide § 460.200, CPG 7132.16.) While Petitioners suggest that before the enactment of FDAMA compounding was illegal, there are no court decisions or statutes that found or made compounding, within the traditional practice of retail pharmacy, illegal. By enacting FDAMA, Congress clarified that compounding within the traditional practice of pharmacy is outside the FDA's jurisdiction. Thus, pursuant to FDAMA, compounded drugs are clearly not new drugs that are subject to FDA approval.

c. Contrary to the claim of Petitioners (Petition, 4-6), before the enactment of Sections 353a(a) and (c), there were no restrictions on the advertising and promotion of compounded drugs by pharmacists or pharmacies. Petitioners' discussion of the CPG at pages 4-6 of their Petition is irrelevant to the First Amendment issues before this Court inasmuch as Petitioners themselves conceded that "Section 353a superseded FDA's policy guide on drug compounding." (Petitioners' Opening Brief in the Ninth Circuit, 12.) The CPG was never law, but simply an unenforceable internal FDA guide for field agents that was not applicable to, or enforceable against, regulatees. Moreover, the courts have not hesitated to declare illegal

the enforcement policies of the FDA based upon its internal guidelines. *See, e.g., FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (invalidating on First Amendment grounds FDA's regulations over tobacco); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (invalidating on First Amendment grounds FDA regulation regarding diet supplements); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) (invalidating on First Amendment grounds policies of FDA and HHS restricting off-label uses of FDA-approved drugs and devices); *Washington Legal Found. v. Friedman*, 36 F. Supp. 2d 16 (D.D.C. 1999); *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999) (finding FDA's policies restricting the dissemination of articles and texts relating to off-label use in violation of the First Amendment), *vacated at* 202 F.3d 331 (D.C. Cir. 2000) because FDA conceded on appeal that it had no authority to prosecute manufacturers for violating a normative standard set forth in FDAMA or in the guidelines for continuing medical education.

d. Petitioners claim (Petition, 4-5) that prior to the enactment of FDAMA, the FDA was enforcing the Food, Drug and Cosmetic Act in a way that is consistent with Sections 353a(a) and (c). Petitioners erroneously represent that all that Congress did in enacting those sections was to codify the law that existed prior to the enactment of those sections. Hence, Petitioners argue those sections are not unconstitutional. Petitioners are incorrect. First, there was no constitutional challenge to the way FDA enforced the CPG prior to the enactment of FDAMA, and the assertion that their enforcement was not unconstitutional is without legal support. Second, in support of their

argument, Petitioners rely upon *United States v. Sene X Eleemosynary Corp.*, 479 F. Supp. 970 (S.D. Fla. 1979) and *Cedars N. Towers Pharmacy, Inc. v. United States*, [1978-79 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,200 (S.D. Fla. Aug. 28, 1978). These cases do not support Petitioners' claim. Neither *Sene X* nor *Cedars* raised any First Amendment issues; and even if they had, both were decided before *Central Hudson & Gas Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980) and the litany of other persuasive commercial speech cases cited at pp. 5-7, *infra*.

3. Contrary to Petitioners' suggestion that "the widespread distribution of drugs that have not first been shown to be safe and effective poses substantial health risks," (Petition, 17), there was *no evidence* whatsoever offered in this case, and no studies of any sort presented or relied upon, to support the claim that the compounding of drugs by licensed pharmacists such as Respondents, in response to a licensed physician's prescription, constitutes a safety hazard. Nor was there any evidence offered or studies adduced to support Petitioners' contention that the total ban on truthful solicitation and advertising "of any particular drug, class of drug or type of drug" will in any way contribute to public health.

REASONS FOR DENYING THE PETITION

Rule 10 of the Supreme Court states that "[A] petition for certiorari will be granted only for compelling reasons." Sup. Ct. R. 10. A petition for a writ of certiorari is rarely granted in a case such as this one "when the error

consists of * * * the misapplication of a properly stated rule of law." *Id.*

This is a classic case of when a petition for certiorari should not be granted. In this case, the parties agree, and two district judges[2] and the unanimous Ninth Circuit held that the controlling rule of law to be applied in this case is the four-part test enunciated in *Central Hudson & Gas Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Petitioners, however, claim that two district judges who ruled on this case and the unanimous Ninth Circuit misapplied the rule of law set forth in *Central Hudson*.

This Court has made it abundantly clear in cases that span a twenty-five year history that absolute prohibitions upon truthful commercial speech, such as those that exist in this case, are unconstitutional. *See, e.g., Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001) (invalidating on First Amendment grounds regulations prohibiting certain outdoor advertising for smokeless tobacco and cigars and regulations involving point-of-sale advertising); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999) (invalidating on First Amendment grounds 18 U.S.C. § 1304 and FCC's implementing regulation that prohibited, *inter alia*, radio and television broadcasters from carrying advertising about privately operated commercial casino gaming, regardless of the station's location); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484

[2] Judge Johnnie B. Rawlinson was a district court judge of Nevada at the time she granted Respondents' motion for a temporary restraining order. Since then she has been a judge on the Ninth Circuit.

(1996) (invalidating on First Amendment grounds two Rhode Island statutes that prohibited the advertising of alcoholic beverage retail prices anywhere other than at point of purchase); *Rubin v. Coors*, 514 U.S. 476 (1995) (invalidating on First Amendment grounds federal statute that prohibited brewers from disclosing on labels the alcoholic content of their beers); *Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994) (invalidating on First Amendment grounds Florida regulation that prohibited certain truthful advertising by certified public accountant); *City of Cincinnati v. Discovery Network*, 507 U.S. 410 (1993) (invalidating on First Amendment grounds city ordinance that prohibited the distribution of commercial publications through freestanding news racks located on public property); *Edenfield v. Fane*, 507 U.S. 761 (1993) (invalidating on First Amendment grounds Florida rule that prohibited certified public accountants from engaging in direct, in-person, uninvited solicitation); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) (invalidating on First Amendment grounds Ohio disciplinary rule that prohibited certain truthful advertising but upholding rule to the extent that advertising fails to disclose pertinent facts); *Bolger v. Youngs Drugs Products Corp.*, 463 U.S. 60 (1983) (invalidating on First Amendment grounds 39 U.S.C. § 3001(3)(2) which prohibited the unsolicited mailings to individual's homes concerning contraceptives); *In re R.M.J.*, 455 U.S. 191 (1982) (invalidating on First Amendment grounds rule of Missouri Code of Professional Responsibility that prohibited certain truthful advertising by attorney); *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980) (invalidating on First Amendment grounds New York

Public Service Commission order that electric utilities in New York State cease all advertising that promotes the use of electricity); *Carey v. Population Services Int'l*, 431 U.S. 678 (1977) (invaliding on First Amendment grounds a New York statute that prohibited, *inter alia*, the advertisement or display of contraceptives); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977) (invalidating on First Amendment grounds truthful advertising of routine legal services); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976) (invalidating on First Amendment grounds Virginia statute that bars advertising prescription drug prices).

The only exceptions to this rule occurred in two circumstances that do not apply in this case. First, this Court has permitted a ban on truthful advertising where the conduct being advertised is illegal. In *United States v. Edge Broad. Co.*, 509 U.S. 418, 421 (1993), this Court held that "federal statutes that prohibit[ed] the broadcast of lottery advertising by a broadcaster licensed to a state that [did] not allow lotteries, while allowing such broadcasting by a broadcaster licensed to a state that sponsors a lottery," did not violate the First Amendment. Because Respondents' compounding is not illegal under any state or federal law, *Edge* is inapplicable.

Second, in three cases this Court has permitted a *limited* restriction on truthful commercial speech. In two of these cases, *Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001) and *Florida Bar v. Went For It*, 515 U.S. 618 (1995), there were significant studies presented to support the limited prohibitions on commercial speech. No such studies were presented or relied upon in this case. Moreover, in *Lorillard*, this Court, while invalidating on First

Amendment grounds certain prohibitions on outdoor advertising and point-of-sale advertising regulations, upheld a Massachusetts statute that prohibited the sale of tobacco products without direct contact with a salesperson because "Massachusetts [sought] to regulate the placement of tobacco products for reasons *unrelated to the communication of ideas*." 121 S. Ct. at 2429 (emphasis added). Similarly, in *Florida Bar*, a 5-4 decision, this Court upheld a Florida Bar Rule that prohibited personal injury lawyers from sending targeted direct-mail solicitations to victims and their relatives *for 30 days* following an accident or disaster. 515 U.S. at 635.

By contrast, the unprecedented, unlimited speech and advertising restrictions upon truthful speech found to be unconstitutional by two federal judges and the unanimous Ninth Circuit in this case were not supported by *any* studies, depositions, affidavits or any testimony in the record. Moreover, those restrictions relate solely to the communication of ideas, and they are not, as in *Lorillard*, focused on the protection of minors from demonstrably harmful conduct.

Finally, in *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 449 (1978), a case decided before *Central Hudson*, this Court upheld application of Ohio disciplinary rules to lawyers who in-person solicited potential personal injury clients "at the hospital room or the accident site, or any other situation that breeds undue influence by attorneys or their agents or runners." Nothing in the present case has anything to do with situations that breed "undue influence."

Petitioners state that because "the court of appeals has held an Act of Congress unconstitutional [t]hat action alone warrants this Court's review." (Petition, 25.) Petitioners cite *United States v. Gainey*, 380 U.S. 63 (1965) for that proposition. That is not a fair reading of that case. In *Gainey*, this Court upheld, on Fifth Amendment grounds, two federal statutes that permitted conviction for certain illegal activities based upon a person's unexplained presence at an illegal still. Unlike this case, there was not a clear line of precedent for the Court to rely on. In that context, this Court said that it "granted certiorari * * * to review the exercise of the grave power of annulling an Act of Congress." 380 U.S. at 65. The Court did not say that whenever an Act of Congress is held unconstitutional "that alone warrants the Court's review." If that had been intended, then Supreme Court Rule 10 would have so provided. In fact, this Court has denied petitions for a writ of certiorari where both federal and state statutes have been declared unconstitutional by the lower courts. *See, e.g., Voinovich v. Women's Med. Prof'l Corp.*, 523 U.S. 1036 (1998) (state statute); *Day v. Holahan*, 513 U.S. 1127 (1995) (state statute); *Children's Legal Found. v. Action for Children's Television*, 503 U.S. 913 (1992) (FCC order); *Curran v. Muller*, 493 U.S. 1074 (1990) (state statute); *Nolasco v. United States*, 502 U.S. 833 (1991) (federal statute, 18 U.S.C. § 3013, held unconstitutional by Ninth Circuit).

In this case, Petitioners have had their positions heard and reviewed separately by two federal judges, and three judges of the Ninth Circuit, one of whom is the Chief Judge. Each judge followed this Court's decisions and rejected Petitioners' arguments. Petitioners also filed

a motion for reconsideration in the Ninth Circuit and that, too, was denied. Petitioners do nothing more than disagree with how the courts below applied *Central Hudson*. This is a classic claim of "the misapplication of law" which merits the denial of certiorari.

This Court does not sit as yet another circuit court of appeals to review the decisions of the lower courts because the Petitioners disagree with the outcome. This case raises not one new principle of law. Every time lower courts unanimously find legislation to violate this Court's clear admonition in *Central Hudson*, it is not an invitation to request this Court once again to review the decisions of the lower courts. We respectfully suggest that governmental bodies must follow the law that this Court has settled in twenty-five years of precedent. No clearer message can be sent than by a simple denial of certiorari in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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